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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,681	06/27/2003	David Wynn	MCP-5016 NP	8293

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EXAMINER

STITZEL, DAVID PAUL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/608,681	WYNN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David P. Stitzel, Esq.	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

## OFFICIAL ACTION

### *Restriction/Election*

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1. Claims 1, 5, 6, 12 and 14 are generic to a plurality of disclosed patentably distinct species of pharmaceutically active ingredient (i.e., celecoxib). The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different chemical and physical properties. Therefore, restriction for examination purposes as indicated is proper.

*Even though this requirement is traversed, Applicants are required under 35 U.S.C. § 121 to elect a single disclosed patentably distinct species of pharmaceutically active ingredient (i.e., celecoxib) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1, 5, 6, 12 and 14 are generic. Applicant should also include a chemical structure of the elected compound, if a chemical structure of said compound is not already contained within the instant specification.*

2. Claims 1-3, 7-9 and 14-16 are generic to a plurality of disclosed patentably distinct species of hydroxyalkylcellulose (i.e., hydroxypropylmethylcellulose). The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different chemical and physical properties. Therefore, restriction for examination purposes as indicated is proper.

*Even though this requirement is traversed, Applicants are required under 35 U.S.C. § 121 to elect a single disclosed patentably distinct species of hydroxyalkylcellulose (i.e.,*

*hydroxypropylmethylcellulose) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claims 1-3, 7-9 and 14-16 are generic.*

3. Claim 4 is generic to a plurality of disclosed patentably distinct species of carbohydrate (i.e., xylitol). The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different chemical and physical properties. Therefore, restriction for examination purposes as indicated is proper.

*Even though this requirement is traversed, Applicants are required under 35 U.S.C. § 121 to elect a single disclosed patentably distinct species of carbohydrate (i.e., xylitol) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently, claim 4 is generic.*

#### ***Conclusion to Restriction Requirement***

*Applicants are advised that a fully responsive reply to this requirement must include an explicit identification of a single disclosed patentably distinct species of: pharmaceutically active ingredient (i.e., celecoxib); hydroxyalkylcellulose (i.e., hydroxypropylmethylcellulose); and carbohydrate (i.e., xylitol), that is elected consonant with this requirement, and a listing of all claims, including any claims subsequently added thereto, which are readable upon the elected species. An argument that a claim is allowable or that claims are not generic is considered nonresponsive unless accompanied by an explicit election of a specific species and subspecies. See 37 C.F.R. § 1.143.*

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species and subspecies to be obvious variants over one another or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other inventions.

If claims are added after the election, Applicant must explicitly indicate which claims are readable upon the elected species. See MPEP § 809.02(a). Amendments submitted after final rejection are governed by 37 CFR 1.116, whereas amendments submitted after allowance are governed by 37 CFR 1.312.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named Inventors is no longer an actual Inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See MPEP § 812.01.


#### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see <http://pair-direct.uspto.gov>. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*May 2, 2006*

  
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